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EXAMINER

GODDARD, LAURA B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,269

Applicant(s)

THORPE ET AL.

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 23, 51, 52 and 93-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 18, 23, 95 and 98 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-17, 19, 51, 52, 93, 94, 96, 97 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

1. Claims 1-19, 23, 51, 52 and 93-99 are pending and are currently under prosecution.

Claim Objections

Claims 8, 18, and 23 appear to be free of the art but are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9, 11, 93, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "**substantially**." This renders the claims indefinite because the term "**substantially**" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

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3. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "Table 4" or "Table 3". It is unclear exactly what Applicant is referring to.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 51, 52, and 96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a **pharmaceutical composition comprising a purified antibody, wherein said antibody binds to phosphatidylserine and is monoclonal antibody 3SB, 9D2, or 3G4**, does not reasonably provide enablement for a composition comprising a purified antibody, or antigen-binding fragment thereof, wherein said antibody binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine wherein said composition is a pharmaceutically acceptable composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening.

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However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a composition comprising a purified antibody, or antigen-binding fragment thereof, wherein said antibody binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine wherein said composition is a pharmaceutically acceptable composition, this means the claims are drawn to a composition for the **treatment of patients** that comprises **any antibody or fragment** that binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine.

The specification contemplates pharmaceutical compositions as therapeutic agents for the treatment of tumors and viral infections (p. 4, p. 26; p.

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33; p. 130; p. 147). The specification discloses the anti-phosphatidylserine antibodies 3SB, BA3, and D11 (produced by Rote et al, Clin Immunol Immunopathol, 1993, 66:193-200), new antibodies 9D2, 1B12, 3G4, 3B10, 1B9, 2G7, 7C5 (Table 4), and antibodies produced by Umeda et al (J of Immunology, 1989, 143:2273-2279) as disclosed on pages 65-66 of the specification, of which only the monoclonal antibodies 3SB, 9D2, and 3G4 have demonstrated anti-tumor effects *in vivo* (p. 252-258; Figs 6, 7, and 8) and 3G4 demonstrated anti-viral effects *in vivo* (Example XXI and Fig. 27). The specification discloses that some of the antibodies taught by prior art may actually be pathogenic (p. 63, lines 33-35; p. 64, lines 7-35; p. 65, lines 33-34 to p. 66, lines 1-2 and 12-14).

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide guidance or examples of **any other** antibodies or antigen-binding fragments that effectively compete with monoclonal antibody 3G4 and could predictably be used as a pharmaceutical for the treatment of cancer or viral infections, other than antibody 3G4. Although the specification enables a pharmaceutical composition comprising antibodies 3SB and 9D2 because they have demonstrated anti-tumor effects without evident pathology, it is not clear from the specification that these antibodies would effectively compete with monoclonal antibody 3G4 for binding to phosphatidylserine because there is no direct competition assay provided and it is unclear if antibodies 3SB and 9D2 bind to the same epitope as 3G4.

Considering the different phospholipids specificities of antibodies 3G4, 3SB, and 9D2 (Table 4), their different relative affinities for phosphatidylserine (Table 3),

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and their different relative inhibitory effects on endothelial cells *in vitro* (Example XVIII and Fig. 16), it appears that antibodies 3G4, 3SB, and 9D2 have different properties, indicating that they may bind to different epitopes and that antibodies 3SB and 9D2 may not effectively compete with 3G4 for binding to phosphatidylserine.

Regarding antibodies for the treatment of cancer, Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Mellman (The Scientist, 2006, 20:47; internet pages 1-10) teaches that therapeutic vaccines for cancer have proven disappointing and that the objective clinical response rate for roughly 1,000 patients fell below an unimpressive 4% in 2004. Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the broadly claimed antibody or antigen-binding fragment, except for 3SB, 9D2, and 3G4 could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging

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promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the broadly claimed antibody or antigen-binding fragment, except for 3SB, 9D2, and 3G4 could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. In addition, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time. Also, the target cell must not have an alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The agent may be inactivated *in vivo* before producing a sufficient

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effect, for example, by degradation, immunological activation or due to an inherently short half-life of the agent. In addition, the agent may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the agent has no effect, circulation into the target area may be insufficient to carry the agent and a large enough local concentration may not be established.

Although the specification discloses the antibodies 3SB, 9D2, and 3G4 that would function in a pharmaceutical composition, the specification does not teach how to make any other antibodies or antigen-binding fragments that would effectively compete for binding to phosphatidylserine with monoclonal antibody 3G4 and would function as claimed and contemplated in the specification as a pharmaceutical. There is no teaching set forth drawn to common structures required of the antibody or antigen-binding fragment that allow the antibody to predictably function in a pharmaceutical composition. For example, Maneta-Peyret et al (J of Immunological Methods, 1988, 108:123-127) teach polyclonal antibodies raised against phosphatidylserine and it would be expected that a subset of these antibodies would effectively compete with 3G4 for binding to phosphatidylserine, however, the specification discloses that antibodies produced using immunization methods such that Maneta-Peyret et al used could result in the production of antibodies that would actually cause pathology (p. 63, lines 33-35; p. 64, lines 7-35; p. 65, lines 33-34; and p. 66, lines 12-14). Thus, one could not predictably distinguish those antibodies that would function as claimed from those that would not. Although Applicant may argue that it is

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possible to screen for antibodies which would effectively compete with 3G4 for binding to phosphatidylserine and function as a pharmaceutical, screening assays do not enable the claimed invention because the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays, are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that a composition comprising a purified antibody, or antigen-binding fragment thereof, wherein said antibody binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine wherein said composition is a pharmaceutically acceptable composition will predictably function as disclosed. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claim 1, 93, 94, and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Maneta-Peyret et al (J of Immunological Methods, 1988, 108:123-127)

The claims are drawn to a composition comprising a purified antibody, wherein said antibody binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine (claim 1), a composition comprising a purified anti-phosphatidylserine antibody, wherein said antibody binds substantially to the same epitope as the monoclonal antibody 3G4 (claim 93), a composition comprising a purified antibody that binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine (claim 94), and a purified antibody wherein said antibody binds to phosphatidylserine and effectively competes with the monoclonal antibody 3G4 for binding to phosphatidylserine (claim 97).

Maneta-Peyret et al teach a polyclonal antibodies that bind to phosphatidylserine (see pages 124-127; Figure 3; abstract). It would be expected that a subset of the polyclonal antibodies taught by Maneta-Peyret et al would bind to substantially the same epitope as antibody 3G4 and effectively compete with antibody 3G4 for binding to phosphatidylserine, hence all of the limitations of the claims are met.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

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granted by a patent and to prevent possible harassment by multiple assignees. **A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).** See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 7, 9-17, 19, 51, 93, 94, 96, and 97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending **Application No. 10/642,124**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application is the same antibody of the immunoconjugate and anti-viral composition of Application 10/642,124. The claims of Application 10/642,124 are drawn to composition comprising an immunoconjugate of the antibody, which anticipates the genus of antibody in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus."

The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408,

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411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 7, 9-17, 19, 51, 93, 94, 96, and 97 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending **Application No. 10/642,122**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application is the same antibody of the immunoconjugate and anti-viral composition and kit of Application 10/642,122. The claims of Application 10/642,122 are drawn to composition comprising an immunoconjugate of the antibody, which anticipates the genus of antibody in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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8. Claims 1, 7, 9-17, 19, 51, 93, 94, 96, and 97 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending **Application No. 10/642,060**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application is the same antibody of the anti-viral composition and kit of Application 10/642,060.

The claims of Application 10/642,060 are drawn to composition comprising the same anti-phosphatidylserine antibody, which anticipates the genus of antibody in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-6, 9-17, 19, 51, 93, 94, 96, and 97 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending **Application No. 10/642,099**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application is the same antibody of the immunoconjugate of Application 10/642,099. The claims of Application 10/642,099 are drawn to composition comprising an

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immunoconjugate of the antibody, which anticipates the genus of antibody in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 9-17, 19, 51, 93, 94, 96, and 97 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending **Application No. 10/642,064**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application is the same antibody of the antibody comprised in the liposome of Application 10/642,064. The claims of Application 10/642,064 are drawn to a liposome comprising the anti-phosphatidylserine antibody, which anticipates the genus of antibody in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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11. Claims 1, 93, 94, and 97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending **Application No. 10/642,118**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody claimed in the instant Application has the same variable regions required for binding to phosphatidylserine as the antibody claimed in Application 10/642,118. The claims of Application 10/642,118 are drawn to an antibody that binds to phosphatidylserine and comprises the variable regions of the heavy and light chains of monoclonal antibody 3G4, which anticipates the genus of antibody in the pending claims that would bind to phosphatidylserine and effectively compete with monoclonal antibody 3G4. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-7, 9-17, 19, 51, 52, 93, 94, 96, 97, and 99 are rejected. Claims 8, 18, and 23 are objected to. Claims 95 and 98 appear to be allowable.

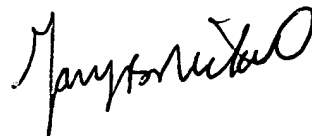
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
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**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**